

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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| REC'D 04 APR 2005 |
| WIPO PCT |

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| Applicant's or agent's file reference 12373860/EJH/ar | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No. PCT/AU2003/001586 | International Filing Date (day/month/year) 28 November 2003 | Priority Date (day/month/year) 29 November 2002 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 14/705, 16/28; C07H 21/04; C12N 15/63; C12Q 1/06; A61K 38/17. | | |
| Applicant THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OF MERCY IN QUEENSLAND et al. | | |

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| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p style="padding-left: 40px;">These annexes consist of a total of sheet(s).</p> |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> |

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| Date of submission of the demand 27 May 2004 | Date of completion of the report 11 March 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer MARIE-ANNE FAM Telephone No. (02) 6283 2254 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims - | YES |
| | Claims 1-26 | NO |
| Inventive step (IS) | Claims - | YES |
| | Claims 1-26 | NO |
| Industrial applicability (IA) | Claims 1-26 | YES |
| | Claims - | NO |

2. Citations and explanations (Rule 70.7)**Novelty and Inventive Step**

The following documents were identified in the International Search Report:

- D1 Tissue Antigens
- D2 WO 2001/036463
- D3 WO 2002/022802
- D4 WO 2002/066600
- D5 WO 2000/078962
- D6 AAH22279
- D7 AAD01646
- D8 AAF89957
- D9 AAH39971
- D10 AAH28091
- D11 AAM19099
- D12 AAH28199
- D13 AAH25395
- D14 BAB26251
- D15 AAM19097
- D16 AAH06801
- D17 AAH19814
- D18 AAM19096
- D19 BAC77074

Document D19 was published prior to the international filing date of the present application, but later than the priority date claimed. Under PCT guidelines this document is excluded from consideration during international preliminary examination, however D19 is nevertheless included here for the purpose of information. This is based on the assumption that the claimed priority date is valid. Should the priority date subsequently be found invalid, then D19 may become relevant during national examination. (See also supplemental box).

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D1 discloses an amino acid sequence that is identical to the present Sequence Id. No. 2 and 4 (see in particular figure 2). Sequence Id. No. 4 described in D2 has 97% similarity to the present Sequence Id. No. 4. D3 discloses an amino acid sequence with 83% identity to the present Sequence Id. No. 8 (see Sequence Id. No. 57). Sequence Id. No. 49 described in D4 has 100% similarity to the present Sequence Id. No. 10. D5 discloses an amino acid sequence with 97% similarity to the present Sequence Id. No. 12 (see Sequence Id. No. 2 and 4). D1-D5 also describe nucleic acids that encode the aforementioned amino acid sequences, vectors comprising the nucleic acids, host cells containing the vectors and the like. Consequently claims 1-26 are not novel or inventive in view of these documents.

D6 discloses a sequence that is identical to the present Sequence Id. No. 2 and has 70% similarity to the present Sequence Id. No. 4.

D7 describes a sequence that is identical to the present Sequence Id. No. 4 and has 70% similarity to the present Sequence Id. No. 2.

D8 discloses a sequence with 100% similarity to the present Sequence Id. No. 4 and 72% similarity to the present Sequence Id. No. 2.

D9 describes a sequence with 72% similarity to the present Sequence Id. No. 6 and 100% similarity to the present Sequence Id. No. 22.

D10 discloses a sequence with 98% similarity to the present Sequence Id. No. 12.

D11 describes a sequence with 98% similarity to the present Sequence Id. No. 14 and 28.

D12 discloses a sequence with 83% similarity to the present Sequence Id. No. 14 and 28.

D13 and D14 describe sequences with 79% and 100% similarity respectively to the present Sequence Id. No. 16.

D15 and D16 disclose sequences with 77% and 74% similarity respectively to the present Sequence Id. No. 18.

D17 describes a sequence with 100% similarity to the present Sequence Id. No. 24 and 90% similarity to the present Sequence Id. No. 27.

D18 discloses a sequence with 100% similarity to the present Sequence Id. No. 26 and 90% similarity to the present Sequence Id. No. 27.

Consequently claims 1-10 and 15 are not novel or inventive in light of D6-D18.

Claims 11-14 are also not inventive in view of D6-D18, since it would be a routine matter for the skilled addressee to obtain antibodies that bind to the polypeptides disclosed in these documents.

Industrial Applicability

Claims 1-26 meet the requirements for industrial applicability.